Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Two Additional Questions; Final Guidance for Industry and FDA Staff

Document issued on December 11, 2002

This document provides two additional questions to the *Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff*, July 6, 2001.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs
Division of Device User Programs and Systems Analysis

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance, contact Lily Ng at 301-594-2812 or by email to lxn@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at (http://www.fda.gov/cdrh/ohip/guidance/1427.pdf) or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1427 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Two Additional Questions; Final Guidance for Industry and FDA Staff

Background

On August 14, 2000, the Food and Drug Administration released a document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" to provide guidance to third-party and hospitals reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third-party and hospital reprocessors of single-use devices (SUDs) are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements (Section 513 and 515 of the Act; 21 *Code of Federal Regulations* Parts 807 and 814).

Since its release on August 14, 2000, the agency has received numerous questions about the enforcement priorities guidance. The following question and answer is meant as clarification of the original document. This guidance will be updated as the need arises.

The Least Burdensome Approach

We believe FDA should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman.

Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at: http://www.fda.gov/cdrh/ombudsman/

Questions related to
REGISTRATION AND DEVICE LISTING

Question: *My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to add the establishment operation type of "Reprocessor of Single-Use Devices" to our existing registration information?*

Answer: Yes, your establishment needs to be registered for all of the operations that are being performed at the same location.

Question: *My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to update our existing device listing information?*

Answer: Yes, your establishment needs to have all of the operations that are being performed on a particular device listed with FDA.